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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/484,542	06/07/1995	MARK L. BRADER	X-10097	4610

7590 08/20/2003

LYNN D APELGREN  
ELI LILLY AND COMPANY  
PATENT DIVISION/LDA  
LILLY CORPORATE CENTER  
INDIANAPOLIS, IN 46285

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

40

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/484,542

Applicant(s)

BRADER ET AL.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4/29/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-32, 57, 58 and 60-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32, 57, 58, 60-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 39.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/03 has been entered.

### ***Information Disclosure Statement***

The IDS submitted 4/29/03 (Paper No. 39) has been considered. The initialed Form 1449 is attached to this correspondence

### ***Claim Rejections - 35 USC § 112***

Claims 32 and 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 has been amended to be directed to a composition comprising a particular insulin AND a particular insulin analog. Claim 28 upon which it depends is directed to a composition comprising insulin OR and insulin analog. As such, this claim and those that depend upon it are improperly dependent and confusing.

Likewise, claim 60 has been amended to be directed to a composition comprising a particular insulin AND a particular insulin analog. Claim 27 upon which it depends is directed to a composition comprising insulin OR and insulin analog. As such, this claim is improperly dependent and confusing.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-28 and 65-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,922,675.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical formulations claimed in Baker et al. ('675) are encompassed by the claims of the instant application. As such, the claims of the patent and application are directed to overlapping embodiments.

### ***Claim Rejections - 35 USC § 102***

Claims 27-28, 60, and 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandenburg et al. (U.S. Patent No. 3,907,763).

Brandenburg et al. discloses insulin derivatives having substituents at Lys B29 from 1 to 15 carbons in length. The derivatives can be crystallized from solutions containing zinc salts. (See at least claim 27; Example 1; column 2, line 44, through column 3, line 15; and column 8, lines 48-50.) The instant specification indicates that any derivative having a carbon atom chain

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length of at least 6 would be considered a fatty acid. Myristic acid (C14) is within the carbon atom chain length disclosed.

Claims 27-28 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Smyth (U.S. Patent No. 3,868,357).

Smyth teaches B29 substituted insulin derivatives. Acyl groups are especially convenient blocking groups. It is preferred that substituents contain no more than about 6 to about 8 carbons. The insulin derivatives can be formulated with zinc and in solution at physiological pH. (See column 1, lines 37-42; column 2, lines 20-21 and 46-47; column 3, lines 37-60; and column 5, table.) The instant specification indicates that any derivative having a carbon atom chain length of at least 6 would be considered a fatty acid.

Claims 27-32, 58, 60, and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (U.S. Patent No. 5,922,675).

The declaration filed on 21 August 1998 under 37 CFR 1.131 was sufficient to overcome the Baker et al. (U.S. Patent No. 5,693,609) reference with respect to claims 27-35. (See discussion in Paper No. 17. Notably zinc is not recited as a limitation in the patent claims and as such a 1.131 declaration is permissible for the present claims.)

However, the claims as amended now encompass compositions of insulin analogs with zinc. As set forth in Paper No. 21, Baker et al. (U.S. Patent No. 5,922,675) has claims to compositions of acylated insulin analogs and zinc. A declaration under 37 CFR 1.131 cannot be used to overcome this reference.

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Baker et al. ('675) is applied as was Baker ('609) in Paper No. 17. The '675 patent is a continuation of the '609 patent and as such their disclosures are the same. An acylated insulin analog where B30 is Thr is taught and claimed. Acylated Lys at position B29 is disclosed. Myristic acid (C14) is disclosed. (See claims and columns 2-4.)

Claims 27-32, 57-58, and 60-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Havelund et al. (U.S. Patent No. 5,750,497) or Havelund et al. (U.S. Patent No. 6,011,007).

This rejection is maintained for reasons of record. Claims 61 and 65-67 are directed to myristoyl derivatives. See at least claim 39 of the '007 patent and at least Examples 15 and 18 of the '497 patent. Also, the acylated des(B30) and B30 where B30 is Ala or Thr human insulin analogs are disclosed.

Applicant's submission under 37 CFR 1.608(b) is noted. However, none of the claims is presently in condition for allowance. It is further noted that claims 61-67 would be rejected under 35 U.S.C. 135(b) as not being made prior to one year from the date on which U.S. Patent Nos. 5,750,497 and 6,011,007 were granted. See *In re McGrew*, 120 F.3d 1236, 1238, 43 USPQ2d 1632, 1635 (Fed. Cir. 1997) where the Court held that the application of 35 U.S.C. 135(b) is not limited to *inter partes* interference proceedings, but may be used as a basis for *ex parte* rejections. Note that claims specifically directed to myristic acid or myristoyl were not presented prior to the response filed 4/29/03.

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***Claim Rejections - 35 USC § 103***

Claims 28 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandenburg et al. in view of either Havelund et al. (U.S. Patent No. 5,750,497) or Havelund et al. (U.S. Patent No. 6,011,007).

Brandenburg et al. is applied as above. It does not teach inclusion of a phenolic compound or glycerol in the composition. However, Brandenburg et al. does suggest inclusion of conventional additives in the pharmaceutical composition.

Havelund et al. ('497 and '007) are applied as before.

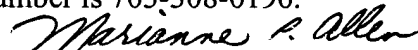
It would have been obvious to include a phenolic compound and glycerol in the composition of Havelund et al. Havelund et al. makes clear that these are conventional additives as set forth in Paper No. 36.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa